Rev Port Cardiol. 2017;36(9):595–597

Revista Portuguesa de
Cardiologia
Portuguese Journal of Cardiology
www.revportcardiol.org

EDITORIAL COMMENT

# Mission (almost) impossible☆

## Missão (quase) impossível

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Available online 12 September 2017

The article by Lobo et al. in this issue of the *Journal*[1] aims to ''compare access to new health technologies to treat coronary heart disease (CHD) in the health systems of Portugal and the US, characterizing the needs of the populations and the resources available''. Their analysis of access to these new technologies (drugs and medical devices) is based on differences between the dates of approval or marketing in the two countries. The article is interesting, informative and original.

There are two points to be considered at the outset. Firstly, the article has 12 co-authors, seven of whom work with CINTESIS, the Center for Research in Health Technologies and Services (of whom only one – Bruno Melica – is a cardiologist), two are from the Portuguese Institute for Environmental Health (ISAMB), and three work in Boston, USA. CINTESIS[2] is a new strategic national research and development unit that aims to strengthen Portugal's science and technology system through cost-effective but highly complex research to meet the societal challenges of the Horizon 2020 program. It has a regional impact, since it involves six institutions in four regions in the north, center and the Algarve. One of its research lines, known as TL1, is clinical and health services research, and the present article is within this ambit. This large virtual institution is unique in Portugal, with 16 research groups able to carry out translational research and innovation in the real-world healthcare environment. ISAMB[3] is a new autonomous multidisciplinary research unit that brings together contributors from various research centers and institutions of the Faculty of Medicine of the University of Lisbon to carry out research, dissemination and social intervention in the field of health sciences. This, to the best of my knowledge, is the first article involving these two institutions in the area of cardiology. I am also unaware of the level of the authors' knowledge of actual cardiological practice in Portugal, and the article's reference list does not shed light on this question. But the article appears to spring from the creation in 2015 of a national system for health technology assessment (SiNATS),[4] focusing on drugs and medical devices, under the aegis of the Portuguese National Authority for Medicines and Health Products (INFARMED), which seeks to harmonize Portugal's health system with that of other European nations.

The second point of interest is that the article compares data from countries with very different characteristics. The population of the US is thirty times larger than Portugal's; healthcare accounts for 10% of gross national product in Portugal and 18% in the US; the literacy rate is also lower in Portugal (95% in 2011 compared to 99% in the US in 2003), as is health literacy; and overall mortality is higher in Portugal (11% vs. 8% in 2014).[5] Epidemiological data and available resources also differ greatly between the two countries. Comparing Portugal and the US is at first sight a considerable challenge that is by no means guaranteed to succeed, since, for example, Portugal lacks reliable epidemiological data, especially on CHD (the PULSAR registry[6] being one of the few exceptions), while data on the US are available from the National Health and Nutrition Examination Survey,[7] which regularly publishes national data with a much greater degree of reliability.

Without going into the details of the Portuguese data, including their sources or how they were collected, it appears that risk profiles are lower than in the US, which

☆ Please cite this article as: Seabra Gomes R. Missão (quase) impossível. Rev Port Cardiol. 2017;36:595–597.

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may explain the lower per capita hospitalization rates and mortality from CHD and myocardial infarction (MI) in Portugal. It is impossible to ascertain the prevalence of CHD in Portugal; except for the high prevalence of hypertension in the country, rates of all other risk factors are lower than in the US. As global coronary risk is lower in Portugal, there is a significant difference in overall mortality from CHD (72.8 age- and gender-adjusted deaths per 100 000 population in Portugal vs. 168 in the US in 2010). We may wonder whether the data on CHD-related mortality in Portugal are accurate. Information on mortality outside hospital may be incorrect; for example, sudden death is rarely recorded as CHD-related, usually being considered as due to stroke, and only recently have death certificates begun to be properly completed, making diagnoses more credible. It is estimated that 82% of individuals who died from MI in 2006 did so outside hospital.[8] There is no significant difference in MI-related mortality between Portugal and the US, which may be due to lower global risk and the fact that medical care, both pre- and in-hospital, and hospital facilities are adequate in Portugal and comparable to those in the US. Primary angioplasty rates have increased (despite the small number of centers with 24-hour catheterization facilities), reaching 338 per million population in 2013.[9] The number of centers offering interventional cardiology in Portugal is relatively low (25), while only 69 offer cardiac surgery. It does not therefore seem feasible to compare Portugal and the US in terms of available resources, even considering the relative sizes of the two countries.

With regard to the stated aim of comparing access to new technologies (medical devices and drugs) in the two countries, the article is particularly interesting and informative, and much will be new for most Portuguese cardiologists. CHD was the basis of this comparison, largely because of the rising expenditure on medical devices in this area.

The US serves as a benchmark for Portugal, even though it has an essentially private health system, much higher per capita health expenditure, and a regulatory agency, the Food and Drug Administration (FDA), that is a worldwide reference for assessment of medical devices and drugs, while the Portuguese health system is basically public, and within the European Union (EU) each country can have completely different regulations and practices, depending on the effectiveness of the regulatory process, limitations on reimbursement, individual economic capacity, availability of resources, etc. Portuguese physicians are generally unaware of the process by which drugs are assessed, approved and marketed, and tend to think that the CE (Conformité Européenne) mark is all that is required for a medical device to be used in Portugal. The article by Lobo et al. is particularly enlightening in this regard.

It is telling that a national system for health technology assessment (SiNATS)[4] was only introduced in 2015. The study by Lobo et al. thus aimed to assess access to new health technologies before the implementation of SiNATS. I do not know whether the system is already functioning in the field, but it is clear that differences between Portugal and the US will remain. It is also not clear whether implementation of the system will speed up or further complicate the process of assessment, approval and marketing of drugs and medical devices. One reason for the earlier introduction and adoption of new health technologies in Portugal, as in Europe generally, compared to the US, may be because all that is needed is the CE mark, although in Portugal high-risk devices also need to be registered with INFARMED before entering the market.

The article states that more than 70% of drugs are marketed sooner after approval in the US than in Portugal and other European countries, whereas the approval and marketing process in the EU is faster for medical devices (12 out of the 16 devices included in the study were approved earlier in Portugal). On this point, the contrast between Portugal and the US is interesting, but it is hard to tell whether this is merely a curiosity or whether it actually affects the quality of healthcare, leaving aside the fact that new technologies may be more cost-effective.

The European Medicines Agency (EMA) authorizes marketing of drugs in the EU, but centralized approval is only compulsory for certain medications. In 2012, the EMA was only responsible for issuing 13% of marketing approvals of drugs in Portugal.

Like other countries, Portugal has in recent years suffered cuts to healthcare expenditure, not only in the budgets for hospitals, health centers and staff, but also in funds for approval and marketing of new drugs and medical devices. Regarding drugs, the government states that generics are identical to the original brand (although this is not always true, as for example the original brand Lasix is much more effective than generic furosemide for both outpatient and in-hospital use), and there are incentives for pharmacies and physicians to prescribe them. It is thus difficult for new drugs to gain approval, as well as to decide on whether to reimburse them and their recommended cost, before they enter the market and their efficacy is confirmed.

Before SiNATS began operating, the introduction of new medical devices in Portugal was relatively straightforward. The main stumbling-block was generally cost, but this was an issue for hospitals, which had to decide whether a new device could be covered by the institution's budget, a decision that in turn depended on the extent to which the hospital's administration prioritized the provision of the best and latest health care for their patients. Typical examples would be prosthetic aortic valves for percutaneous implantation, left atrial appendage closure devices, and new absorbable stents. Assessment and approval of new medical devices in Europe does not require randomized trials, which is the main reason that they are brought to market earlier than in the US. Despite this advantage, there are many cases of post-marketing safety alerts and recalls of devices in Europe, due to insufficient time and experience before marketing, in contrast to the requirement by the FDA in the US for clinical trials. This question is currently under discussion in the European Parliament, which is investigating changes in regulation.[10]

The article by Lobo et al. is highly informative, even though a comparison between Portugal and the US, in healthcare as in any other area, is an almost impossible mission.

The main message is that differences between the two countries, with drugs being approved earlier and devices being available sooner in Portugal, may have contributed to improvements in healthcare in this country, reducing the disparities between Portugal and the US in epidemiological risk profiles.

## Conflicts of interest

The author has no conflicts of interest to declare.

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